

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant:** Eugenio Cefali, et al.  
**Serial No.:** 08/960,557  
**Filing Date:** 31 October 1997  
**Docket Number:** 50454-56103USCIP  
**Title:** METHODS FOR TREATING HYPERLIPIDEMIA WITH  
INTERMEDIATE RELEASE NICOTINIC ACID COMPOSITIONS  
HAVING UNIQUE BIOPHARMACEUTICAL CHARACTERISTICS  
**Art Unit:** 1615  
**Examiner:** J.M. Spear  
**Date:** 4 January 2005

**Mail Stop 313(c)**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the enclosed Form PTO-1449. Copies of the listed documents are also enclosed.

REMARKS

The cited documents include experts reports exchanged in the pending litigation involving Kos Pharmaceuticals, Inc. and Barr Laboratories, Inc. ("Consolidated Case No. 02 CV 1683"), and articles and documents cited in those reports to the extent that they have not yet been considered by the Examiner. To the extent the cited documents are subject to the protective order in Consolidated Case No. 02 CV 1683, they are being submitted for consideration under MPEP § 724. In addition, to the extent the cited documents contain information confidential to Barr Laboratories, Inc. and to any third parties to Consolidated Case No. 02 CV 1683, they are being submitted in redacted form.

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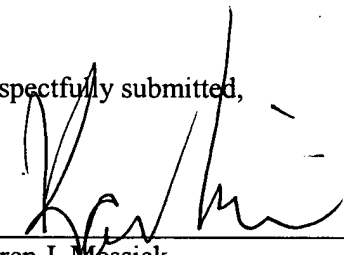
Any fee required in connection with this paper should be charged to Deposit Account 50-2543. A duplicate of this paper is enclosed.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Form PTO-1449 be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached at (954) 331-3825. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

  
\_\_\_\_\_  
Karen J. Messick  
Attorney for Applicants  
Registration No. 46,256

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Suite 300  
Weston, FL 33326

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Fax: 954.331.3867

Date: 1/4/05

FORM PTO 1449 (modified)			ATTY DOCKET NO. <b>5045-56103USCIP</b>			APPLICATION NO. 08/960,577		
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			APPLICANT Eugenio Cefali, et al.					
LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)			FILING DATE 31 October 1997				GROUP <b>1615</b>	
U.S. PATENT DOCUMENTS								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES/NO/ OR ABSTRACT	
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)								
<b>DOCUMENTS SUBMITTED UNDER MPEP § 724</b>								
		<b>Expert Report of Cheryl D. Blume, Ph.D. (January 27, 2004)</b> <b>- Subject to Protective Order</b>						
		<b>Expert Report of Dr. Sergio Fazio (February 4, 2004) [Redacted Version]</b> <b>- Subject to Protective Order</b>						
		<b>Rebuttal Expert Report of Dr. Sergio Fazio (April 2, 2004)</b> <b>- Subject to Protective Order</b>						
		<b>Expert Report of Dr. Sergio Fazio Regarding</b> <b>U.S. Patent No. 6,676,967 (August 17, 2004)</b> <b>- Subject to Protective Order</b>						
		<b>Expert Report of Don W. Martens (February 6, 2004) [Redacted Version]</b> <b>- Subject to Protective Order</b>						
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		<b>Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version]</b> <b>- Subject to Protective Order</b>						
		<b>Expert Report of Dr. Joseph R. Robinson Regarding</b> <b>U.S. Patent No. 6,676,967 (August 18, 2004)</b> <b>- Subject to Protective Order</b>						
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OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)			
<b>DOCUMENTS SUBMITTED UNDER MPEP § 724</b>			
		<b>Sample Kos Clinical Trial Medical Consent Form</b> <b>- Subject to Protective Order</b>	
		<b>Sample Kos Clinical Trial Investigator's Statement</b> <b>- Subject to Protective Order</b>	
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	<b>Carl J. Lavie, et al., <i>Marked Benefit with Sustained-Release Niacin Therapy in Patients with "Isolated" Very Low Levels of High-Density Lipoprotein Cholesterol and Coronary Artery Disease</i>, Am. J. Cardiol. 1992:69:1083-1085</b>
	<b>Excerpts from the 1993, 2000 and 2002 editions of the Physician's Desk Reference</b> 1993 edition (pp. 434, 611, 856, 1189, 1919, 1920, 2491 and 2492) 2000 edition (pp. 1519-1523) 2002 edition (pp. 1846-1850)
	<b><i>Niacin: Double-edged Sword for Lowering Cholesterol</i>, Tufts University Diet &amp; Nutritional Letter (Tufts Univ., Boston, MA), August 1994, Vol. 12, issue 6</b>
	<b>Larsen, ML and Illingworth, DR, <i>Drug Treatment of Dyslipoproteinemia</i>, Med Clin N Am., 78:225-245 (1994)</b>
	<b>Lavie, Letter to Editor, JAMA 1994; 272:513-515</b>
	<b>Keenan, Letter to Editor, JAMA 1994; 272:513-515</b>
	<b>Shields &amp; Beckmann, Letter to Editor, JAMA 1994; 272:513-515</b>
	<b>Thomas N. Tozer, <i>Clinical Pharmacokinetics Concepts and Applications</i> (3d ed. 1995) at Chapter 9, p. 120</b>
	<b>Excerpts from the 1995 United States Pharmacopeia (pp. iii-vi, 1080-1082, 1793-1799, 1940-1944)</b>
	<b>Morgan &amp; Capuzzi Abstract, <i>Safe and Effective Treatment of Dyslipidemia by Niaspan, a New Sustained-Release Niacin</i>, Clinical Pharmacology &amp; Therapeutics (February 1996)</b>
	<b>Morgan &amp; Capuzzi Article, <i>Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial</i>, J. Cardiovasc. Pharmacol. Therapeut. 1(3):195-202 (July 1996)</b>

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OTHER DOCUMENT(S) (Including Author, Title, Date, Periodical Name, etc.)			
	<b>Capuzzi DM, et al., <i>Efficacy and Safety of An Extended-Release Niaspan: A Long-Term Study</i>, Am J Cardiol. 1998;82:74U-81U</b>		
	<b>Guyton JR, <i>Advances in Dyslipidemia: Discussion Session II</i>, Am J Cardiol, 1998: 82(12A): 85U-86U</b>		
	<b>Knopp RH, et al., <i>Equivalent Efficacy of a Time-Release Form of Niacin (Niaspan) Given Once-a-Night Versus Plain Niacin in the Management of Hyperlipidemia</i>, Metabolism 47:1097-1104 (1998)</b>		
	<b>American Diabetes Association: <i>Management of Dyslipidemia in Adults with Diabetes</i>, Diabetes Care 21:179-182, 1998</b>		
	<b>Elam MB, et al., <i>Effect of Niacin on Lipid and Lipoprotein Levels and Glycemic Control in Patients With Diabetes and Peripheral Arterial Disease</i>, JAMA: 2000; 284:1263-1270</b>		
	<b>Kesala R, et al., <i>Niacin (N) vs. Niaspan (NS) Treatment of the Atherogenic Lipid Profile (ALP; Small, Dense LDL, HDL2, HDLc and Triglycerides) and Lp(a) in Diabetic Patients (DP)</i>, Diabetes 49 (suppl. 1): A268 at 1114-P (June 2000)</b>		
	<b>2001 NCEP Report at VI-11, Table VI.2-3</b>		
	<b>Wang, W. et al., <i>Effect of Nicotinic Acid Administration on Hepatic Very Low Density Lipoprotein-Triglyceride Production</i>, Am J Physiol Endocrinol Metab., 280:E540-E547 (2001)</b>		
	<b>Smith SC, et al., <i>AHA/ACC Guidelines for Preventing Heart Attack and Death in Patients with Atherosclerotic Cardiovascular Disease: 2001 Update</i>. AHA/ACC Scientific Statement, 1577-79</b>		
	<b>Tavintharan S and Kashyap M, <i>The Benefits of Niacin in Atherosclerosis</i>, Curr Athero. Reports 2001; 3:74-82</b>		
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		<b>Meadows M., <i>Serious Liver Injury: Leading Reason for Drug Removals, Restrictions</i>, FDA Consumer Magazine, May-June 2001;  <a href="http://www.fda.gov/fdac/features/2001/301_liver.html">http://www.fda.gov/fdac/features/2001/301_liver.html</a></b>	
		<b>Grundy SM, et al., <i>Efficacy, Safety, and Tolerability of Once-Daily Niacin for the Treatment of Dyslipidemia Associated with Type 2 Diabetes</i>. Arch Intern Med. 2002; 162: 1568-1576</b>	
		<b>American Diabetes Association: <i>Management of Dyslipidemia in Adults with Diabetes</i>, Diabetes Care 25:S74-S77, 2002</b>	
		<b>Pan J, et al., <i>Niacin Treatment of the Atherogenic Lipid Profile and Lp(a) in Diabetes, Diabetes, Obesity and Metabolism</i> 4:255-261 (2002)</b>	
		<b>Pan J, et al., <i>Extended-Release Niacin Treatment of the Atherogenic Lipid Profile and Lipoprotein(a) in Diabetes</i>, Metabolism 51:1120-1127 (2002)</b>	
		<b>Meyers CD, et al., <i>Varying Cost and Free Nicotinic Acid Content in Over-the-Counter Niacin Preparations for Dyslipidemia</i>, Ann Intern Med. 2003; 139:996-1002</b>	
		<b>CDER Guidance for Industry, <i>Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations</i> (March 2003)</b>	
		<b>American Diabetes Association: <i>Dyslipidemia Management in Adults with Diabetes</i>, Diabetes Care 27:S68-S71, 2004</b>	
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